DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 21, 2015

Telemed Solutions, Inc.
Ken Burns
CEO
6251 Schaefer Avenue, Suite K
Chino, California 91710

Re: K142349
Trade/Device Name: TM eCloud ECG Analysis System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, KRE, MLO, DPS, DXH, OUG
Dated: August 11, 2015
Received: August 13, 2015

Dear Ken Burns,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Telemed Solutions

Indications for Use

Device Name: TM eCloud ECG Analysis System

1. Indications for Use:

The TM eCloud ECG Analysis System, using proprietary algorithm, is intended for use in adults and children of any age from birth upwards. The Program makes significant use of the patient's age and gender and will provide a unique diagnosis if age differs only by a few days in the case of neonates. It is a program that is based on normal limits derived using the algorithm itself with this applying to criteria for subjects of all ages, including neonates.

TM eCloud ECG Analysis System is qualified to evaluate, detect, and aid in the physician diagnosis of the following cardiac arrhythmias and/or conduction defects:

- Evaluation of symptoms that may be caused by cardiac arrhythmia and /or conduction disturbances
- Evaluation of symptoms that may be due to myocardial ischemia
- Detection of ECG events that alter prognosis in certain forms of heart disease
- Detection and analysis of indirect pacemaker function and failure
- Determination of cardiac response to lifestyle
- Evaluation of therapeutic interventions
- Investigations in epidemiology and clinical trials
- Evaluation of heart rate variability in the assessment of heart disease

TM eCloud ECG Analysis System is intended to provide an interpretation of up to 12-channel ECG in all situations including resting and ambulatory ECG including Holter, cardiac event, and mobile cardiac telemetry. This software qualifies to be used in hospitals, physician offices, and scanning services. It is designed for acquisition, analysis, edit, review, report and storage of all ECG and multi-parameter data. It is capable of diagnosing all commonly recognized ECG abnormalities such as myocardial infarction (MI), acute MI, ventricular hypertrophy, abnormal ST-T changes, lethal arrhythmias, and common rhythm abnormalities.

TM eCloud ECG Analysis System can analyze recordings performed on newborns, children, and adults.

TM eCloud ECG Analysis System's interpretation results are not intended to be the sole means of diagnosis for any abnormal ECG that may be detected. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG.

Telemed Solutions

Prescription Use ____X_____ and/or Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please Do Not Write Below This Line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Telemed Solutions

5-1 510(k) Summary of Safety and Effectiveness

1. General Information

Submitter:

Company	**Telemed Solutions Inc.**
Address	6251 Schaefer Ave, Suite K
	Chino, CA 91710
Contact:	Ken Burns
Telephone:	(909) 628-8787
Date Prepared:	March 5, 2015

Device:

Trade Name:	**TM eCloud ECG Analysis System**
Common Name:	ECG Analysis Software (per 21 CFR 870.1425)
Classification Name:	Programmable Diagnostic Computer
Product Code:	DQK, KRE, MLO, DPS, DXH, OUG
Regulation:	21 CFR 870.1425, 870.36, 870.2800, 870.2340, 870.2920, 880.6310
Class:	II

2. Predicated Devices:

The legally marketed predicated devices to which equivalence is being claimed is:

GE Healthcare.	MARS Holter Analysis Workstation	K132437
Agilent Technologies	2010 Plus Holter for Windows	K003940
Medtronic, Inc.	Paceart Optima™ System Software	K110693
Memtec Corporation	MobileECG	K103427

Telemed Solutions

3. Device Description:

The TM eCloud ECG Analysis System consists of a (1) server-side, application Platform as a Service (PaaS) cloud based system, a (2) desktop client-side application, and (3) a web-based Physician Portal website.

The (1) server-side, application PaaS component collects, stores, performs arrhythmia analysis on ECG uploads, and transfers data to and from the client-side application.

The (2) desktop client-side application is a workstation system which allows technicians to review ECG, edit the analysis results produced by the (1) server-side, application PaaS component, and generate reports for the ECG study. The edited results and reports are uploaded to the (1) server-side, application PaaS component. It also allows notifications and updates to (3) Physician Portal website.

The TM eCloud ECG Analysis System is capable of processing and performing arrhythmia analysis on ten seconds to 60 days of recorded ECG from one to 12 channels. The system is designed to be compatible with any stationary or ambulatory ECG device having the ability to export ECG. Typical compatible devices interfaces include Cardiac Mobile Telemetry, Event recorders, and Holter recorders but is not limited to a particular ECG device. ECG interfaces from desperate devices are translated by Telemed Adapters which convert proprietary formats to the Physionet WFDB MIT format but vendors may choose to provide the Physionet WFDB directly and bypass the use of an adapter.

The purpose of the TM eCloud ECG Analysis System is to determine if any irregular rhythms, irregular beats, conduction defects, or ST depression occurred during the recording or monitoring. A qualified physician can then use the results of the analysis report to determine what action needs to be taken to help the patient reduce or prevent the occurrence of these abnormalities.

The users may upload ECG to the TM eCloud ECG Analysis System via a cellular network, REST web service, or FTP from any computer or cellular equipment. The system performs analysis on the uploaded ECG using the proprietary 12 Lead Diagnostic EKG Analysis Engine or proprietary algorithm Reduced Lead 1-7 lead Analysis Engine and downloads the results to the client.

If detected, the ECG engine will report on the following arrhythmias: ventricular ectopy, atrial ectopy, pauses, heart block, junctional rhythms, hemiblock, LBBB, RBBB, ST anomalies, and prolonged QT. It will display up to 900 statements including atrial fibrillation, ventricular fibrillation/flutter, and WPW.

The (2) client workstation software employs several screens to display the ECG data. These screens include: 5-Minute View, Hourly view, or Daily view, 8-Second View, Arrhythmias Only View, time and frequency domain HRV, ST changes, AF burden. All analyzed data is saved in a database. From there data can be organized into a report that can be printed on paper or distributed electronically.

Although the analysis engine reports arrhythmias and abnormalities with a high rate of accuracy, all results need to be reviewed and/or edited by a qualified medical professional.

Telemed Solutions

4. Indications for Use:

The TM eCloud ECG Analysis System, using a proprietary algorithm, is intended for use in adults and children of any age from birth upwards. The Program makes significant use of the patient's age and gender and will provide a unique diagnosis if age differs only by a few days in the case of neonates. It is a program that is based on normal limits derived using the algorithm itself with this applying to criteria for subjects of all ages, including neonates.

The TM eCloud ECG Analysis System is qualified to evaluate, detect, and aid in the physician diagnosis of the following cardiac arrhythmias and/or conduction defects:

- Evaluation of symptoms that may be caused by cardiac arrhythmia and /or conduction disturbances
- Evaluation of symptoms that may be due to myocardial ischemia
- Detection of ECG events that alter prognosis in certain forms of heart disease
- Detection and analysis of indirect pacemaker function and failure
- Determination of cardiac response to lifestyle
- Evaluation of therapeutic interventions
- Investigations in epidemiology and clinical trials
- Evaluation of heart rate variability in the assessment of heart disease

The TM eCloud ECG Analysis System is intended to provide an interpretation of up to 12-channel ECG in all situations including resting and ambulatory ECG including Holter, cardiac event, and mobile cardiac telemetry. This software qualifies to be used in hospitals, physician offices, and scanning services. It is designed for acquisition, analysis, edit, review, report and storage of all ECG and multi-parameter data. It is capable of diagnosing all commonly recognized ECG abnormalities such as myocardial infarction (MI), acute MI, ventricular hypertrophy, abnormal ST-T changes, lethal arrhythmias, and common rhythm abnormalities.

The TM eCloud ECG Analysis System can analyze recordings performed on newborns, children, and adults.

The TM eCloud ECG Analysis System's interpretation results are not intended to be the sole means of diagnosis for any abnormal ECG that may be detected. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG.

5. Non-clinical Tests Used in Determination of Substantial Equivalence:

Non-clinical tests were performed to compare TM eCloud ECG Analysis System to the predicated devices.

The following applicable standards were used to compare the TM eCloud ECG Analysis System to the predicate devices:

ANSI/AAMI EC57:2012 - Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms.

6. Databases used for Non-Clinical Testing:

- **CSE (Common Standards for Quantitative Electrocardiography) Database** - The CSE database consisted of 1220 ECGs recorded from individuals living in several European countries
- **Glasgow 1000 ECG Database** - The 1000 ECG database was selected to provide a wide range of normal and abnormal ECGs, including arrhythmias, conduction defects, etc.
- **Glasgow Adult Normal Database** - The normal ECG database was composed of ECGs recorded from 1498 apparently healthy individuals who were each examined by a physician and who had no evidence of heart disease or any other condition such as diabetes which might be expected to lead to cardiovascular abnormalities. This database has been used extensively in the determination of normal limits of ECGs such as those relating to the QT interval
- **Glasgow Pediatric ECG Database** - This database of 840 ECGs was recorded from neonates, infants and children referred or admitted to hospital for investigation of various problems.
- **Glasgow Pacemaker ECG Database** - This database was composed of 47 ECGs were selected where the pacemaker stimuli were seen to be correctly detected from inspection of relevant indicators on the ECG printout.
- **Glasgow Atrial Fibrillation Database** - In order to supplement the number of cases of atrial fibrillation, an additional 72 cases were added to the database of 1000 ECGs from which rhythm analysis was assessed.

Reduced lead testing was performed in accordance with *ANSI/AAMI EC57/Ed.3, Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms:*

- Accuracy of QRS detection analysis was tested using ***the*** **MIT-BIH Arrhythmia Database, AHA Database of Evaluation of Ventricular Arrhythmia Detectors, and Noise Stress Test Database**.
- Accuracy of heart rate measurements (HRV) was tested using the **MIT-BIH Arrhythmia Database, AHA Database of Evaluation of Ventricular Arrhythmia Detectors, Noise Stress Test Database, and Congestive Heart Failure RR Interval Database.**
- Accuracy of VEB detection analysis was tested using the **MIT-BIH Arrhythmia Database, AHA Database of Evaluation of Ventricular Arrhythmia Detectors, and Noise Stress Test Database**
- Accuracy of Ventricular Flutter or Fibrillations was tested using the **MIT-BIH Arrhythmia Database, AHA Database of Evaluation of Ventricular Arrhythmia Detectors, and Creighton University Ventricular Tachyarrhythmia Database (CU)**
- Accuracy of supraventricular ectopic beats and Atrial Flutter or Fibrillations was tested using the **MIT-BIH Arrhythmia Database and Noise Stress Test Database**

- Accuracy of ST segment deviations or to detect ST changes was tested using the **European ST-T Database**

7. Conclusions from Non-clinical Testing

After comparing predicated devices to Telemed Solutions' TM eCloud ECG Analysis System, results show that with the intended use, the software is equivalent in safety and effectiveness. Therefore Telemed Solutions supports a claim: TM eCloud ECG Analysis System is substantially equivalent to the predicate devices.